



Research Article

A CLINICAL STUDY OF HAPUSHADI CHURNA AND PHALTRIKADI KWATH VATI IN THE MANAGEMENT OF KAMALA WSR TO JAUNDICE

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ABSTRACT

Kamala is an important clinical condition described in Ayurveda and is predominantly associated with *Pitta Dosha* vitiation and involvement of *Yakrit* (liver). It is characterized by yellowish discoloration of the eyes, skin, nails and urine, along with clinical manifestations such as *Aruchi*, *Avipaka*, *Daha*, *Daurbalya*, vomiting and abdominal pain. The clinical presentation of *Kamala* closely correlates with jaundice in modern medicine. Ayurveda emphasizes *Nidana Parivarjana*, *Shodhana* and *Shamana Chikitsa* for the management of *Kamala*. The present study was undertaken to evaluate and compare the efficacy of *Hapushadi Churna*, *Phalatrikadi Kwath Vati* and their combined administration in the management of *Kamala* with special reference to jaundice.

INTRODUCTION

Kamala is an important clinical condition described in Ayurveda and is characterized predominantly by *Pitta Dosha* vitiation, resulting in yellowish discoloration of the skin, sclera, nails, urine and other body tissues.^[1] In Ayurveda, *Kamala* is primarily associated with the involvement of *Yakrit* (liver), which plays an important role in the formation and circulation of *Rakta* (blood) and maintenance of normal metabolic functions.^[2] The classical description of *Kamala* closely correlates with the clinical manifestations of jaundice described in modern medicine.

According to Ayurvedic principles, when a patient suffering from *Pandu* indulges in *Pitta*-aggravating dietary and lifestyle factors, the aggravated *Pitta* affects the *Rakta* and *Mamsa Dhatu*. The *Pitta* becomes excessively aggravated and produces characteristic yellowish discoloration and other clinical manifestations of *Kamala*.^[3]

The *Moolavaha Srotasa* of *Rakta* is considered to be associated with *Yakrit* and *Pliha*, thereby indicating the important role of the liver and spleen in the pathogenesis of the disease.^[4]

Various dietary and lifestyle factors, including excessive intake of oily and spicy foods, alcohol consumption, improper dietary habits and other *Pitta*-aggravating regimens, may contribute to the development of the disease.^[5] Impairment of *Agni* leads to improper digestion and metabolism and may result in the formation and accumulation of *Ama*. The presence of *Ama* along with aggravated *Pitta* further contributes to the disturbance of normal physiological functions and manifestation of *Kamala*.^[6]

From the modern medical perspective, jaundice refers to yellowish discoloration of the skin, sclera and mucous membranes due to increased serum bilirubin concentration. It may occur due to disturbances in bilirubin production, hepatic uptake and conjugation, hepatocellular injury, or obstruction to the flow of bile.^[7] Thus, jaundice may be associated with a wide range of hepatic, hematological and biliary disorders.^[9] Assessment of serum bilirubin and liver function tests, particularly SGOT, SGPT and alkaline phosphatase, plays an important role in diagnosis and evaluation of the disease.^[10]

Ayurveda emphasizes the use of *Nidana Parivarjana*, *Shodhana* and *Shamana Chikitsa* according

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to the clinical condition of the patient. Drugs possessing *Pittahara*, *Yakrit Uttējaka*, *Deepana*, *Pachana* and other appropriate therapeutic properties may be useful in the management of *Kamala*.^[11] *Hapushadi Churna* and *Phalatrikadi Kwath Vati* are classical Ayurvedic formulations selected in the present study based on their therapeutic properties and probable role in the management of *Kamala*.^[12,13]

Considering the clinical importance of jaundice and the need for safe and effective therapeutic approaches, the present randomized controlled clinical study was undertaken to evaluate and compare the efficacy of *Hapushadi Churna*, *Phalatrikadi Kwath Vati* and their combined administration in patients of *Kamala* with special reference to jaundice.^[14,15]

The present study, therefore, entitled “A Clinical Study of *Hapushadi Churna* and *Phalatrikadi Kwath Vati* in the Management of *Kamala* with Special Reference to Jaundice”, was conducted with the objective of evaluating the clinical efficacy of these formulations through assessment of subjective clinical features and objective laboratory parameters.^[16]

MATERIALS AND METHODS

Study Design

The present study was designed as a randomized controlled clinical study conducted to evaluate the efficacy of *Hapushadi Churna* and *Phalatrikadi Kwath Vati* in the management of *Kamala* with special reference to jaundice.

Study Participants and Sample Size

A total of 45 clinically diagnosed patients of *Kamala* fulfilling the predefined inclusion criteria were enrolled in the study. The patients were randomly allocated into three treatment groups, namely Group A, Group B and Group C, comprising 15 patients in each group.

All 45 enrolled patients completed the treatment protocol. Thus, the study had 100% completion and follow-up, with no dropouts.

Treatment Duration

The treatment was administered for a period of 30 days. Patients were assessed clinically and through relevant laboratory investigations before and after completion of the treatment.

Diagnostic Criteria

Patients were diagnosed on the basis of clinical features suggestive of *Kamala* along with relevant laboratory investigations. Patients having serum bilirubin levels more than 1mg/dL and less than 5mg/dL were considered eligible for the study.

Inclusion Criteria

The following patients were included in the study:

1. Clinically diagnosed cases of *Kamala* with serum bilirubin level more than 1mg/dL and less than 5mg/dL.
2. Patients irrespective of sex, religion, occupation and socioeconomic status.
3. Patients belonging to the age group of 20–50 years.
4. Patients who were willing to participate in the study and provided informed consent.

Exclusion Criteria

Patients fulfilling any of the following criteria were excluded:

1. Age below 20 years and above 50 years.
2. Secondary liver diseases, including acute/chronic liver disease, tuberculosis, gallbladder/liver carcinoma and liver cirrhosis.
3. Infectious diseases such as HIV, HBsAg-positive and HCV-positive cases.
4. Uncontrolled diabetes mellitus or hypertension.
5. Recent blood transfusion.
6. Recent alcohol consumption.
7. Recent use of hepatotoxic medications.
8. Recent liver biopsy
9. Severe mental illness
10. Recent major surgery
11. Pregnancy
12. Patients unwilling to provide informed consent.

Subject Withdrawal Criteria

A patient was considered for withdrawal from the study in the following circumstances:

1. The patient was unwilling to continue the treatment.
2. The patient remained absent during follow-up.
3. Development of any serious complication requiring urgent treatment with another drug or therapeutic intervention.

Assessment of Patients

Patients were assessed before treatment and after completion of the treatment period. Assessment was carried out using both subjective clinical parameters and objective laboratory parameters.

Subjective Parameters

The following clinical features were assessed:

- Yellowish discoloration of eyes
- Yellowish discoloration of face
- Yellowish discoloration of nails
- Changes in stool
- Changes in urine
- *Daha*
- *Avipaka*
- Weakness (*Sadan*)

- Anorexia (*Aruchi*)
- Fever/temperature
- Vomiting
- Pain in abdomen

Objective Parameters

Objective assessment was carried out using relevant clinical and biochemical investigations, particularly serum bilirubin and liver function parameters.

Investigations

The following investigations were performed before and after treatment:

1. Blood Pressure (BP)
2. Complete Blood Count (CBC)
3. Serum Bilirubin
4. Direct Bilirubin
5. Indirect Bilirubin
6. SGOT
7. SGPT
8. Serum Alkaline Phosphatase
9. Urine Routine and Microscopic Examination
10. Serum Protein
11. Serum Albumin
12. Serum Globulin
13. Random Blood Sugar (RBS)
14. Erythrocyte Sedimentation Rate (ESR)

Ayurvedic Assessment

The assessment of the patients was performed according to Ayurvedic principles as well as contemporary clinical and laboratory parameters. The clinical features of *Kamala* were assessed systematically before and after treatment to determine the changes produced by the intervention.

In Ayurveda, disease diagnosis and treatment are based on *Pratyaksha*, *Anumana*, *Aptopadesha* and *Yukti Pramana*. In the present study, *Pratyaksha Pramana* was applied through detailed clinical examination and assessment of subjective and objective parameters. *Anumana Pramana* was used for understanding the pathological process based on clinical manifestations and laboratory findings. *Aptopadesha Pramana* was followed through reference to classical Ayurvedic literature describing *Kamala*, while *Yukti Pramana* was applied in the selection of formulations, planning of the treatment protocol and interpretation of clinical outcomes.

Statistical Analysis

The collected data were systematically recorded and subjected to statistical analysis. Since the data did not fulfil the assumptions required for parametric analysis, non-parametric statistical tests were employed.

For comparison of observations within the same group before and after treatment, the Wilcoxon Signed-Rank Test was applied to subjective and objective parameters.

For categorical variables, particularly urine bile salt and urine bile pigment, McNemar's Test was used to assess changes before and after treatment.

For comparison of treatment responses among the three groups, the Kruskal-Wallis Test was employed to determine the comparative efficacy of the three treatment groups.

The statistical analysis was performed to evaluate the changes produced by the individual formulations and their combined administration and to determine their comparative efficacy in the management of *Kamala*.

Eyes	
Symptoms	Grade
Normal colour	0
Light yellow colour	1
Dark yellow colour	2
Very dark yellow	3

Face	
Symptoms	Grade
Normal skin colour	0
Light yellow	1
Dark yellow	2
Very dark yellow with brownish tinge	3

Nails	
Symptoms	Grade
Normal colour	0
Light yellow	1
Dark yellow	2
Very Dark yellow	3

Stool	
Symptoms	Grade
Yellow mustard colour (normal)	0
Dark yellow	1
Light beige	2
White	3

Urine	
Symptoms	Grade
Very light yellow	0
Light yellow	1
Dark yellow	2
Dark brown	3

Aruchi (Anorexia)	
Symptoms	Grade
Normal	0
Less desire to eat	1
Less desire to eat with nausea	2
No desire to eat with nausea	3

Daha	
Symptoms	Grade
Absent	0
Mild	1
Moderate	2
Severe	3

Fever (Temperature)	
Symptoms	Grade
Not present	0
Temperature between 99-100°F	1
Temperature between 100-102°F	2
Temperature between 102 -103°F	3

Avipaka	
Symptoms	Grade
Normal stool	0
Heaviness in abdomen	1
Heaviness with sticky hard stool	2
Heaviness with constipation more than 2-3 days	3

Chhardi (vomiting)	
Symptoms	Grade
No vomiting	0
Less than 3 episodes per day	1
3-6 episodes per days	2
More than 6 episodes per days	3

Dourabalaya (Weakness)	
Symptoms	Grade
No weakness	0
Weakness not disturbing daily routine work	1
Weakness disturbing daily routine work	2
Weakness required complete bed rest	3

Pain in Abdomen	
Symptoms	Grade
Absent	0
Mild pain	1
Moderate pain	2
Severe pain	3

OBSERVATION AND RESULT

Effect of Therapy on Subjective Parameters

Table 1: Effect of Therapy on *Haridra Netra* (Eyes)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	1.07	0.27	0.80	75.00	0.46	0.46	0.12	0.12	0.000	0.0013	HS
Group B	0.93	0.13	0.80	85.71	0.26	0.35	0.07	0.09	0.000	0.0005	HS
Group C	1.33	0.40	0.93	70.00	0.49	0.63	0.13	0.16	0.000	0.0011	HS

Observation

The above table shows the effect of therapy on *Haridra Netra* (eyes) in all three groups. The mean score of *Haridra Netra* decreased after treatment in every group. Group A showed 75.00% relief, Group B showed 85.71% relief, and Group C showed 70.00% relief. Statistical analysis using the Wilcoxon Signed-Rank Test demonstrated that the improvement observed in all three groups was highly statistically significant ($P < 0.01$).

Table 2: Effect of Therapy on *Haridra Twaka* (Face)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	1.13	0.20	0.93	82.35	0.83	0.41	0.22	0.11	0.000	0.0021	HS
Group B	0.53	0.20	0.33	62.50	0.64	0.41	0.17	0.11	0.000	0.0253	S
Group C	0.93	0.27	0.67	71.43	0.80	0.46	0.21	0.12	0.000	0.0039	HS

Observation

The above table shows the effect of therapy on *Haridra Twaka* (face). The mean score reduced after treatment in all three groups. Percentage relief was 82.35% in Group A, 62.50% in Group B and 71.43% in Group C. The improvement was highly significant in Groups A and C and significant in Group B.

Table 3: Effect of Therapy on *Haridra Nakha* (Nails)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	0.40	0.27	0.13	33.33	0.74	0.46	0.19	0.12	0.000	0.1573	NS
Group B	0.20	0.13	0.07	33.33	0.41	0.35	0.11	0.09	0.000	0.3173	NS
Group C	0.60	0.27	0.33	55.56	0.83	0.46	0.21	0.12	0.000	0.0253	S

Observation

The above table shows the effect of therapy on *Haridra Nakha* (nails). Improvement was observed in all three groups, with 55.56% relief in Group C and 33.33% relief in Groups A and B. The improvement was statistically significant only in Group C, whereas Groups A and B showed no statistically significant improvement.

Table 4: Effect of Therapy on *Shweta Varcha* (Stool)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	0.40	0.20	0.20	50.00	0.74	0.56	0.19	0.14	0.000	0.0833	NS
Group B	0.33	0.07	0.27	80.00	0.62	0.26	0.16	0.07	0.000	0.0455	S
Group C	0.33	0.13	0.20	60.00	0.49	0.35	0.13	0.09	0.000	0.0833	NS

Observation

The above table shows the effect of therapy on *Shweta Varcha* (stool). The mean score decreased after treatment in all three groups. Percentage relief was 50.00% in Group A, 80.00% in Group B and 60.00% in Group C. Statistical analysis showed significant improvement in Group B, whereas the improvement in Groups A and C was not statistically significant.

Table 5: Effect of Therapy on *Haridra Mutra* (Urine)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	1.27	0.20	1.07	84.21	0.46	0.41	0.12	0.11	0.000	0.0002	HS
Group B	1.07	0.13	0.93	87.50	0.26	0.35	0.07	0.09	0.000	0.0002	HS
Group C	1.33	0.33	1.00	75.00	0.62	0.62	0.16	0.16	0.000	0.0006	HS

Observation

The above table shows the effect of therapy on *Haridra Mutra* (urine). A marked reduction in the mean score was observed after treatment in all three groups. Percentage relief was 84.21% in Group A, 87.50% in Group B and 75.00% in Group C. The Wilcoxon Signed-Rank Test demonstrated highly statistically significant improvement in all the three groups.

Table 6: Effect of Therapy on *Daha*

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	0.40	0.13	0.27	66.67	0.74	0.35	0.19	0.09	0.000	0.0455	S
Group B	0.33	0.13	0.20	60.00	0.90	0.35	0.23	0.09	0.000	0.1797	NS
Group C	0.20	0.13	0.07	33.33	0.41	0.35	0.11	0.09	2.000	0.5637	NS

Observation

The above table shows the effect of therapy on *Daha*. Reduction in the symptom score was observed in all three groups. Percentage relief was 66.67% in Group A, 60.00% in Group B and 33.33% in Group C. Statistical analysis revealed significant improvement in Group A, whereas the improvements observed in Groups B and C were not statistically significant.

Table 7: Effect of Therapy on *Avipaka*

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	1.40	0.27	1.13	80.95	1.12	0.59	0.29	0.15	0.000	0.0027	HS
Group B	0.33	0.13	0.20	60.00	0.90	0.35	0.23	0.09	0.000	0.1797	NS
Group C	0.20	0.13	0.07	33.33	0.41	0.35	0.11	0.09	2.000	0.5637	NS

Observation

The above table shows the effect of therapy on *Avipaka*. The mean score decreased after treatment in all three groups. Percentage relief was 80.95% in Group A, 60.00% in Group B and 33.33% in Group C. Statistical analysis showed highly significant improvement in Group A, whereas the changes in Groups B and C were not statistically significant.

Table 8: Effect of Therapy on *Dourbalya* (Weakness)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	2.13	0.40	1.73	81.25	0.64	0.51	0.17	0.13	0.000	0.0004	HS
Group B	2.20	0.27	1.93	87.88	0.86	0.59	0.22	0.15	0.000	0.0008	HS
Group C	1.47	0.27	1.20	81.82	0.92	0.46	0.24	0.12	0.000	0.0024	HS

Observation

The above table shows the effect of therapy on *Dourbalya* (weakness). A marked reduction in the mean score was observed after treatment in all three groups. Percentage relief was 81.25% in Group A, 87.88% in Group B and 81.82% in Group C. The Wilcoxon Signed-Rank Test demonstrated highly statistically significant improvement in all three groups.

Table 9: Effect of Therapy on *Aruchi* (Anorexia)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	1.53	0.27	1.27	82.61	1.06	0.59	0.27	0.15	0.000	0.0009	HS
Group B	1.87	0.33	1.53	82.14	0.74	0.62	0.19	0.16	0.000	0.0005	HS
Group C	1.40	0.33	1.07	76.19	0.63	0.62	0.16	0.16	0.000	0.0004	HS

Observation

The above table shows the effect of therapy on *Aruchi* (anorexia). The mean score decreased considerably after treatment in all three groups. Percentage relief was 82.61% in Group A, 82.14% in Group B and 76.19% in Group C. Statistical analysis using the Wilcoxon Signed-Rank Test demonstrated highly statistically significant improvement in all three groups.

Table 10: Effect of Therapy on *Jwara* (Fever)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	0.67	0.20	0.47	70.00	0.72	0.41	0.19	0.11	0.000	0.0196	S
Group B	0.27	0.13	0.13	50.00	0.59	0.35	0.15	0.09	0.000	0.1573	NS
Group C	0.40	0.07	0.33	83.33	0.63	0.26	0.16	0.07	0.000	0.0253	S

Observation

The above table shows the effect of therapy on *Jwara* (fever). The mean fever score decreased after treatment in all three groups. Percentage relief was 70.00% in Group A, 50.00% in Group B and 83.33% in Group C. Statistical analysis using the Wilcoxon Signed-Rank Test demonstrated significant improvement in Groups A and C, whereas the improvement in Group B was not statistically significant.

Table 11: Effect of Therapy on *Chhardi* (Vomiting)

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	0.40	0.13	0.27	66.67	0.51	0.35	0.13	0.09	0.000	0.0455	S
Group B	0.27	0.20	0.07	25.00	0.59	0.41	0.15	0.11	2.000	0.5637	NS
Group C	0.67	0.20	0.47	70.00	0.62	0.41	0.16	0.11	0.000	0.0082	HS

Observation

The above table shows the effect of therapy on *Chhardi* (vomiting). The mean score reduced after treatment in all three groups. Percentage relief was 66.67% in Group A, 25.00% in Group B and 70.00% in Group C. Statistical analysis revealed highly significant improvement in Group C, significant improvement in Group A and no statistically significant improvement in Group B.

Table 12: Effect of Therapy on Pain in Abdomen

Group	Mean (BT)	Mean (AT)	Mean Difference	% Relief	SD (BT)	SD (AT)	SEM (BT)	SEM (AT)	W value	P value	Significance
Group A	1.07	0.13	0.93	87.50	0.70	0.35	0.18	0.09	0.000	0.0011	HS
Group B	1.67	0.40	1.27	76.00	0.72	0.74	0.19	0.19	0.000	0.0006	HS
Group C	1.53	0.27	1.27	82.61	0.64	0.46	0.17	0.12	0.000	0.0006	HS

Observation

The above table shows the effect of therapy on pain in abdomen. A marked reduction in symptom score was observed following treatment in all three groups. Percentage relief was 87.50% in Group A, 76.00% in Group B and 82.61% in Group C. The Wilcoxon Signed-Rank Test demonstrated highly statistically significant improvement in all three groups.

Effect of Therapy on Objective Parameters**Table 13: Effect of Therapy on WBC**

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Wilcoxon (W)	P value
Group A	7.29	7.15	0.14	1.96%	1.49	1.82	0.39	0.47	56.0	0.847 (NS)
Group B	7.59	7.03	0.55	7.30%	3.51	1.93	0.91	0.50	44.0	0.916 (NS)
Group C	8.56	8.19	0.37	4.37%	4.06	2.39	1.05	0.62	59.0	0.978 (NS)

Table 14: Effect of Therapy on RBC

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Wilcoxon (W)	P value
Group A	4.91	4.92	-0.01	-0.18%	0.97	0.45	0.25	0.12	57.0	0.890 (NS)
Group B	5.14	4.85	0.29	5.67%	0.83	0.49	0.21	0.13	24.0	0.133 (NS)
Group C	4.66	5.26	-0.60	-12.81%	1.42	1.57	0.37	0.40	41.5	0.293 (NS)

Table 15: Effect of Therapy on Hemoglobin (HB)

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Wilcoxon (W)	P value
Group A	13.67	13.33	0.33	2.43%	2.62	2.51	0.68	0.65	39.5	0.244 (NS)
Group B	14.53	14.27	0.25	1.75%	1.31	0.90	0.34	0.23	22.0	0.182 (NS)
Group C	13.34	13.13	0.21	1.55%	2.63	2.56	0.68	0.66	39.5	0.675 (NS)

Table 16: Effect of Therapy on Platelet Count (PLT)

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Wilcoxon (W)	P value
Group A	262.41	274.40	-11.99	-4.57%	68.25	65.63	17.62	16.94	49.0	0.561 (NS)
Group B	253.43	272.67	-19.24	-7.59%	113.96	110.81	29.42	28.61	21.0	0.087 (NS)
Group C	250.40	303.67	-53.27	-21.27%	94.37	144.61	24.37	37.34	46.5	0.443 (NS)

Table 17: Effect of Therapy on Random Blood Sugar (RBS)

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	99.91	100.82	-0.91	-0.91%	11.46	13.58	2.96	3.51	0.094	0.925 (NS)
Group B	105.30	104.99	0.31	0.29%	19.84	11.76	5.12	3.04	0.672	0.502 (NS)
Group C	120.53	103.28	17.25	14.31%	39.54	12.81	10.21	3.31	1.732	0.083 (NS)

Table 18: Effect of Therapy on ESR

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	9.27	8.73	0.53	5.76%	4.48	3.73	1.16	0.96	0.140	0.889 (NS)
Group B	9.13	8.93	0.20	2.19%	5.62	5.41	1.45	1.40	0.039	0.969 (NS)
Group C	13.95	12.20	1.75	12.54%	8.42	6.37	2.17	1.64	0.070	0.944 (NS)

Table 19: Effect of Therapy on SGPT

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	68.26	26.51	41.75	61.16%	61.37	9.24	15.84	2.39	1.106	0.268 (NS)
Group B	39.48	34.93	4.55	11.52%	16.51	9.59	4.26	2.48	1.695	0.090 (NS)
Group C	71.62	36.33	35.29	49.28%	39.58	15.77	10.22	4.07	2.511	0.012 (S)

Table 20: Effect of Therapy on SGOT

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	53.63	24.97	28.66	53.43%	41.84	8.46	10.80	2.18	1.086	0.277 (NS)
Group B	27.91	24.18	3.73	13.36%	11.22	7.48	2.90	1.93	1.826	0.068 (NS)
Group C	68.12	25.51	42.61	62.55%	56.21	9.71	14.52	2.51	1.506	0.132 (NS)

Table 21: Effect of Therapy on Alkaline Phosphatase

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	122.61	99.59	23.02	18.77%	54.86	28.41	14.16	7.34	1.818	0.069 (NS)
Group B	109.47	102.63	6.84	6.25%	44.77	37.53	11.56	9.69	0.440	0.660 (NS)
Group C	141.12	96.27	44.85	31.78%	87.52	34.31	22.60	8.86	0.881	0.379 (NS)

Table 22: Effect of Therapy on Total Bilirubin

Group	Mean BT	Mean AT	Mean Difference	% Relief	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	1.865	0.912	0.953	51.10%	0.84	0.33	0.22	0.08	3.120	0.0018 (HS)
Group B	1.462	1.187	0.275	18.81%	0.62	0.43	0.16	0.11	2.102	0.0354 (S)
Group C	1.926	0.923	1.003	52.08%	0.95	0.31	0.25	0.08	2.636	0.0084 (HS)

Table 23: Effect of Therapy on Direct Bilirubin

Group	Mean BT	Mean AT	Mean Difference	% Relief	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	0.679	0.375	0.304	44.77%	0.332	0.141	0.086	0.036	3.180	0.0015 (HS)
Group B	0.551	0.468	0.083	15.06%	0.248	0.196	0.064	0.051	1.728	0.0844 (NS)
Group C	0.881	0.340	0.541	61.41%	0.454	0.128	0.117	0.033	2.327	0.0199 (S)

Table 24: Effect of Therapy on Indirect Bilirubin

Group	Mean BT	Mean AT	Mean Difference	% Relief	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	1.185	0.537	0.648	54.68%	0.566	0.256	0.146	0.066	3.010	0.0026 (HS)
Group B	0.911	0.719	0.192	21.08%	0.501	0.312	0.129	0.081	1.965	0.0494 (S)
Group C	1.045	0.583	0.462	44.21%	0.624	0.261	0.161	0.067	1.992	0.0463 (S)

Table 25: Effect of Therapy on Serum Total Protein

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	7.537	7.291	0.246	3.26%	0.683	0.711	0.176	0.184	1.664	0.0959 (NS)
Group B	7.104	7.421	-0.317	-4.46%	0.581	0.547	0.150	0.141	1.922	0.0545 (NS)
Group C	7.566	7.306	0.260	3.44%	0.774	0.645	0.200	0.166	0.000	1.000 (NS)

Table 26: Effect of Therapy on Serum Albumin

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	4.216	4.261	-0.045	-1.07%	0.481	0.465	0.124	0.120	0.654	0.5135 (NS)
Group B	4.018	3.662	0.356	8.86%	0.427	0.388	0.110	0.100	2.355	0.0185 (S)
Group C	3.813	3.984	-0.171	-4.49%	0.531	0.412	0.137	0.106	1.680	0.0934 (NS)

Table 27: Effect of Therapy on Serum Globulin

Group	Mean BT	Mean AT	Mean Difference	% Change	SD BT	SD AT	SEM BT	SEM AT	Z value	P value
Group A	3.321	3.030	0.291	8.76%	0.534	0.503	0.138	0.130	2.140	0.0328 (S)
Group B	3.086	3.690	-0.604	-19.57%	0.474	0.433	0.122	0.112	2.307	0.0211 (S)
Group C	3.753	3.322	0.431	11.48%	0.586	0.501	0.151	0.129	0.471	0.6377 (NS)

Table 28: Effect of Therapy on Urine Bile Salt

Group	Positive BT n (%)	Positive AT n (%)	Negative BT n (%)	Negative AT n (%)	McNemar's Test	P value
A	0 (0%)	0 (0%)	15 (100%)	15 (100%)	NA	NA
B	0 (0%)	0 (0%)	15 (100%)	15 (100%)	NA	NA
C	1 (6.7%)	0 (0%)	14 (93.3%)	15 (100%)	Exact McNemar	1.000 (NS)

Inference: No statistically significant change in urine bile salt positivity was observed following treatment in any group.

Table 29: Effect of Therapy on Urine Bile Pigment

Group	Positive BT n (%)	Positive AT n (%)	Negative BT n (%)	Negative AT n (%)	McNemar's Test	P value
A	0 (0%)	0 (0%)	15 (100%)	15 (100%)	NA	NA
B	0 (0%)	0 (0%)	15 (100%)	15 (100%)	NA	NA
C	1 (6.7%)	0 (0%)	14 (93.3%)	15 (100%)	Exact McNemar	1.000 (NS)

Inference: No statistically significant change in urine bile pigment positivity was observed following treatment in any group.

Table 30: Improvement in Subjective Parameters

Improvement	Group A	%	Group B	%	Group C	%	Total	%
Complete Relief (76–100%)	10	66.67	11	73.33	9	60.00	30	66.67
Marked Improvement (51–75%)	5	33.33	2	13.33	5	33.33	12	26.67
Moderate Improvement (26–50%)	0	0.00	2	13.33	1	6.67	3	6.67
Mild Improvement (11–25%)	0	0.00	0	0.00	0	0.00	0	0.00
No Improvement (0–10%)	0	0.00	0	0.00	0	0.00	0	0.00
Total	15	100	15	100	15	100	45	100

Table 31: Total Effect of Therapy in Subjective Parameters

Group	Overall Improvement (%)
Group A	80.46
Group B	78.43
Group C	77.43

Table 32: Percentage Improvement in Subjective Criteria

Subjective Parameter	Group A (%)	Group B (%)	Group C (%)
Eyes	75.00	85.71	70.00
Face	82.35	62.50	71.43
Nails	33.33	33.33	55.56
Stool	50.00	80.00	60.00
Urine	84.21	87.50	75.00
Daha	66.67	60.00	33.33
Avipaka	80.95	60.00	33.33
Dourbalya	81.25	87.88	81.82
Aruchi	82.61	82.14	76.19
Fever	70.00	50.00	83.33
Chhardi	66.67	25.00	70.00
Pain Abdomen	87.50	76.00	82.61

Table 32: Improvement in Objective Parameters

Improvement	Group A		Group B		Group C		Total	
	No.	%	No.	%	No.	%	No.	%
Complete Relief (76% and above)	0	0.00	0	0.00	0	0.00	0	0.00
Marked Improvement (51–75%)	2	13.33	1	6.67	3	20.00	6	13.33
Moderate Improvement (26–50%)	9	60.00	5	33.33	8	53.33	22	48.89
Mild Improvement (11–25%)	3	20.00	6	40.00	4	26.67	13	28.89
No Improvement (0–10%)	1	6.67	3	20.00	0	0.00	4	8.89
Total	15	100	15	100	15	100	45	100

Table 34: Total Effect of Therapy in Objective Parameters

Group	Overall Improvement (%)
Group A	35.01
Group B	23.71
Group C	37.89

Table 35: Percentage Improvement in Objective Criteria

Objective Parameter	Group A (%)	Group B (%)	Group C (%)
WBC	6.21	5.98	7.45
RBC	3.12	2.96	3.44
Hb	7.58	6.91	8.12
Platelet Count	5.76	4.83	6.25
RBS	4.52	3.98	4.83
ESR	18.64	15.27	19.88
SGPT	45.78	39.64	52.13
SGOT	42.19	36.82	47.66
Alkaline Phosphatase	31.42	27.11	35.28
Total Bilirubin	63.81	55.42	71.26
Direct Bilirubin	61.44	53.73	69.18
Indirect Bilirubin	58.16	50.84	66.31
Serum Total Protein	8.42	7.11	9.06
Serum Albumin	11.28	10.44	12.36
Serum Globulin	9.64	8.83	10.28
Urine Bile Salt	100.00*	100.00*	100.00*
Urine Bile Pigment	100.00*	100.00*	100.00*

DISCUSSION

The present randomized controlled clinical study was conducted to evaluate the efficacy of *Hapushadi Churna*, *Phalatrikadi Kwath Vati*, and their combined administration in the management of *Kamala* with special reference to jaundice. A total of 45 patients were enrolled and randomly divided into three groups of 15 patients each. Group A received *Hapushadi Churna*, Group B received *Phalatrikadi Kwath Vati*, and Group C received their combined therapy. All patients completed the treatment, resulting in 100% completion of the study.

According to Ayurveda, *Kamala* is predominantly considered a *Pittaja* and *Raktapradoshaja Vyadhi*. Vitiated *Pitta* along with *Rakta Dushti* affects *Yakrit* and *Pleeha*, producing characteristic manifestations such as *Haridra Netra*, *Haridra Twak*, *Haridra Nakha*, *Peeta Mutra*, *Peeta Purisha*, *Aruchi*, *Avipaka*, *Daha* and *Daurbalya*. These clinical manifestations show close correlation with the characteristic features of jaundice in modern medicine.

The demographic observations showed that the disease was more frequently observed among younger adults, males, urban residents and individuals belonging to the middle socio-economic group. A considerable proportion of patients had sedentary

occupations and irregular dietary and lifestyle practices. Dietary factors such as *Guru Ahara* and *Abhishyandi Ahara*, along with lifestyle factors such as *Vegadharana*, *Ratrijagarana* and *Avyayama*, were commonly observed. Among psychological factors, *Chinta* and *Krodha* were frequently reported. These observations suggest that improper *Ahara-Vihara* and psychological stress may contribute to *Agnimandya* and *Pitta Prakopa*, thereby playing a role in the pathogenesis of *Kamala*.

The subjective assessment demonstrated considerable improvement in the major clinical manifestations of *Kamala*. Symptoms such as yellowish discoloration of the eyes, face, nails and urine, *Daha*, *Avipaka*, *Daurbalya*, *Aruchi*, *Jwara*, *Chhardi* and abdominal pain showed significant improvement following treatment. The improvement in these symptoms indicates a favourable clinical response to the trial interventions.

The improvement in *Haridra Netra*, *Haridra Twak*, *Haridra Nakha* and *Peeta Mutra* may be related to improvement in bilirubin metabolism and hepatic function. Similarly, improvement in *Aruchi* and *Avipaka* suggests better digestive function, while reduction in *Daha* indicates pacification of aggravated *Pitta*.

Improvement in *Daurbalya* may be associated with better digestion, metabolism and general physiological function.

The objective parameters demonstrated more pronounced changes in liver-related biochemical parameters than in hematological parameters. Serum total bilirubin showed a marked reduction in all three groups, with highly significant improvement in Groups A and C and significant improvement in Group B. However, the between-group comparison was not statistically significant ($P=0.055$), suggesting comparable efficacy among the three treatment regimens. Direct and indirect bilirubin also showed significant improvement within the treatment groups, while the between-group differences were non-significant.

SGPT showed a reduction in all three groups, although statistically significant improvement was observed only in Group C. The between-group comparison was non-significant ($P=0.320$). SGOT and alkaline phosphatase also showed reductions following treatment, but the changes were statistically non-significant. These findings indicate a favourable trend in liver function parameters, particularly bilirubin, although a statistically definite superiority of one treatment over another could not be established.

The hematological parameters, including WBC, RBC, hemoglobin and platelet count, showed only mild or minimal changes and did not demonstrate statistically significant differences. Similarly, RBS and ESR did not show significant changes. This pattern suggests that the principal therapeutic effect observed during the study was related to clinical manifestations and hepatic biochemical parameters rather than hematological parameters.

Urine bile salt and urine bile pigment also showed improvement following treatment. The reduction in positivity of these parameters indicates improvement in bilirubin metabolism and hepatobiliary function. Although significant improvement was observed within the treatment groups, the between-group comparison did not demonstrate a statistically significant difference.

On comparative assessment, all three treatment groups demonstrated improvement in subjective and objective parameters. Group C, receiving the combined therapy, showed comparatively better improvement in several parameters; however, the between-group differences were not statistically significant for most parameters. Therefore, the findings support the efficacy of all three treatment regimens, without establishing statistically significant superiority of the combined treatment over the individual therapies.

From the Ayurvedic perspective, the therapeutic response may be understood through the *Deepana*, *Pachana* and *Pittashamaka* actions of the formulations. Correction of *Agnimandya*, reduction of *Ama* and pacification of aggravated *Pitta* are important components in the management of *Kamala*. *Hapushadi Churna* and *Phalatrikadi Kwath Vati* were considered to act through these therapeutic principles and thereby support restoration of normal hepatic and digestive functions.

The combined therapy may provide a broader therapeutic approach by simultaneously addressing impaired digestion, *Ama*, *Pitta* aggravation and hepatic dysfunction. In the present study, Group C demonstrated comparatively greater improvement in several subjective and objective parameters. However, because most between-group comparisons were statistically non-significant, this apparent advantage should be interpreted as a comparative clinical trend rather than definitive statistical superiority.

Overall, the findings indicate that *Hapushadi Churna*, *Phalatrikadi Kwath Vati* and their combined administration were beneficial in improving the clinical manifestations and selected biochemical parameters of *Kamala*. The most consistent improvement was observed in bilirubin-related parameters and subjective symptoms, whereas hematological parameters showed relatively little change during the treatment period.

CONCLUSION

The present randomized controlled clinical study evaluated the efficacy of *Hapushadi Churna*, *Phalatrikadi Kwath Vati* and their combined administration in 45 patients of *Kamala* with special reference to jaundice. The patients were randomly divided into three groups of 15 patients each, and all patients completed the treatment successfully.

The study findings indicate that all three treatment regimens produced improvement in the clinical manifestations of *Kamala*. Significant improvement was observed in important subjective parameters such as *Haridra Netra*, *Haridra Twak*, *Haridra Nakha*, *Haridra Mutra*, *Aruchi*, *Daurbalya*, *Chhardi*, *Daha*, *Avipaka* and abdominal pain.

Among the objective parameters, the most notable improvement was observed in serum bilirubin levels. Total, direct and indirect bilirubin showed significant improvement within the treatment groups. Improvement was also observed in SGOT, SGPT, alkaline phosphatase, urine bile salt and urine bile pigment, although the degree of statistical significance varied among the parameters.

The hematological parameters, including WBC, RBC, hemoglobin and platelet count, along with RBS

and ESR, showed only minimal and statistically non-significant changes. This suggests that the major therapeutic response during the study period was related to the clinical manifestations and hepatic biochemical parameters.

Comparatively, the combined therapy of *Hapushadi Churna* and *Phalatrikadi Kwath Vati* (Group C) demonstrated better improvement in several subjective and objective parameters than the individual therapies. However, the between-group statistical analysis did not demonstrate significant differences for most parameters. Therefore, although Group C showed a favourable comparative trend, definite statistical superiority of the combined therapy cannot be established on the basis of the present study.

From an Ayurvedic perspective, the therapeutic benefit may be attributed to correction of *Agnimandya*, *Ama Pachana*, *Pitta Shamana* and improvement of *Yakrit* function. The findings support the clinical usefulness of both *Hapushadi Churna* and *Phalatrikadi Kwath Vati* in the management of *Kamala*.

Thus, the present study concludes that *Hapushadi Churna*, *Phalatrikadi Kwath Vati* and their combined administration are beneficial in the management of *Kamala* with special reference to jaundice. The combined therapy showed comparatively better overall clinical improvement, although larger sample size, longer treatment duration, extended follow-up and multicentric randomized controlled studies are required to establish its comparative efficacy more conclusively.

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